K021016

JUN 17 2002

GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201 USA

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Pat 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (414) 544-3894
Summary prepared: 21 March, 2002

Identification of Product: AMX-4 Plus Mobile X-Ray System
Classification Name: Mobile X-ray System
Manufacturer: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53118

Device Description: The AMX-4 Plus Mobile X-ray System consists of an X-ray Generator and Control, X-ray Tube, Beam Limiting Device and a new option called the Dose Area Product meter.

Indications for Use: The AMX-4 Plus Mobile X-ray System is designed to perform radiographic x-ray examinations.

Comparison with: AMX-4 Plus Mobile X-ray System is substantially equivalent to the AMX-3 Mobile X-ray System, K802047.

Conformance: The AMX-4 Plus Mobile X-ray System will conform to applicable sections of 21CFR 1020.30 and 1020.31. The system will also conform to UL 2601-1, IEC 601-1, IEC 601-1-2, and IEC 601-1-3.

Conclusions: In the opinion of GE Medical Systems, the AMX-4 Plus Mobile X-ray System is substantially equivalent to the previously marketed AMX-3 Mobile X-ray System, K802047. The AMX-4 Plus does not include any new indications for use, nor does use of this device result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2002

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-709
MILWAUKEE WI 53201

Re: K021016
Trade/Device Name: AMX-4 Plus Mobile X-Ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: March 27, 2002
Received: March 29, 2002

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K021016

Device Name: AMX-4 Plus Mobile X-ray System

Indications for Use

The AMX-4 Plus Mobile X-ray System is indicated for use in generating radiographic images of human anatomy in all general purpose X-ray diagnostic procedures. It may be used in radiology departments, emergency rooms, intensive care units, operating rooms, pediatrics, orthopedics and clinics.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

David A. Clegorn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021016